



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA-2012-N-1210]

RIN 0910-AF22

Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Administrative Docket Update; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; notification.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of certain documents to update the administrative docket of the proposed rule to amend FDA's labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the Nutrition Facts and Supplement Facts labels to assist consumers in maintaining healthy dietary practices.

DATES: We are extending the comment period that was scheduled to close on September 25, 2015, until October 13, 2015.

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. (FDA-2012-N-1210) for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Serena Lo, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2488, email: ConsumerStudiesBranch@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of March 3, 2014 (79 FR 11879), we published a proposed rule that would amend our labeling regulations for conventional foods and dietary supplements to provide updated nutrition information. More recently, in the Federal Register of July 27, 2015 (80 FR 44302), we reopened the comment period through September 25, 2015, for the proposed rule for the sole purpose of inviting public comments on two consumer studies being added to the administrative record. The consumer studies pertained to proposed changes to the Nutrition Facts label formats. We also issued a supplemental proposed rule (80 FR 44303) with a comment period through October 13, 2015. The supplemental proposal included two additional consumer studies pertaining to the declaration of added sugars and alternative footnote statements. We proposed text for the footnotes to be used on the Nutrition Facts label, after completing our consumer research in which we tested various footnote text options for the label, and to establish a Daily Reference Value of 10 percent of total energy intake from added sugars. The supplemental proposal also would require the declaration of the percent Daily Value for added sugars on the label and provide an additional rationale for the declaration of added sugars on the label. We explained that we were taking these actions based, in part, on the science underlying a new report released by the 2015 Dietary Guidelines Advisory Committee.

We have received some comments suggesting we are not eliciting comment on the consumer studies in the supplemental proposal published in July 2015. We clarify in this notice that: (1) The consumer studies on the added sugars declaration and the alternative footnote statements in the supplemental proposal relate to topics on which we sought comment and (2) the consumer studies on the format published in a separate notice in July 2015 were included for comment, and were placed in the docket at that time. We are now responding to additional

requests for the raw data for each of these consumer studies that are relevant to the summary memoranda for the studies, also now available for comment.

II. Updated Information

We are updating the docket for the rulemaking with two additional documents: A request from the Grocery Manufacturers Association for the raw data associated with the four consumer studies described in this document, and our response to that request indicating that we will provide the raw data underlying the four consumer studies to anyone who submits a request to ConsumerStudiesBranch@fda.hhs.gov.

These documents may be seen by interested persons at the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>.

In addition, we are extending to October 13, 2015, the comment period on the two consumer studies pertaining to proposed changes to the Nutrition Facts label formats, which had been scheduled to close on September 25, 2015, to align the comment periods for all consumer studies.

We will continue to take comment on the supplemental proposed rule, including taking comment on the consumer studies on added sugars and the footnote, until October 13, 2015.

Dated: September 3, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-22757 Filed: 9/9/2015 08:45 am; Publication Date: 9/10/2015]